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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/040,518	03/17/1998	COSTAS N. KARATZAS	06632/011001	1912
20583	7590	04/13/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/040,518

Applicant(s)

KARATZAS ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 06 March 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☒ Newly proposed or amended claim(s) 39,40 and 60-63 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 22-24,27-36,39-41 and 44-58.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Anne-Marie Falk, Ph.D.
Primary Examiner
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Continuation Sheet (PTOL-303)**Continuation of 3. NOTE:**

If entered, the proposed amendment would require a new ground of rejection for newly added Claim 59. Claim 59 would be rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The newly added claim is directed, in relevant part, to a transgenic female ruminant comprising germline and somatic cells that comprise a nucleic acid molecule comprising a β -casein promoter operably linked to a nucleotide sequence (said nucleotide sequence further defined in the claim). The enablement rejection of record (see Office Action of 5/3/04 and that of 11/17/05) sets forth a scope of enablement that is limited to use of the mouse WAP promoter to drive expression of the nucleotide sequence recited in the claim. In the remarks submitted 3/6/06 (hereinafter referred to as "the response"), where Applicants assert that "new claim 41 [sic] ... recites a β -casein promoter" it is assumed that Applicants intended to refer to Claim 59. At page 6, paragraph 4 of the response, Applicants assert that this claim is fully enabled because transgenic ruminants expressing dragline silk polypeptides in milk under control of the β -casein promoter have been generated. Applicants point to the Declaration of Dr. Karatzas filed December 3, 2004 at paragraph 6. It is noted that paragraph 6 does not refer to the use of the β -casein promoter in those animals. On the contrary, paragraph 6 pertains only to goats comprising a transgene having the mouse WAP promoter. Although paragraph 4 states that transgenic female ruminants comprising a transgene having the β -casein promoter were generated, there is no information as to how they were generated and there is no evidence presented in the Declaration to suggest that dragline silk polypeptides expressed under the control of the β -casein promoter were expressed in quantities sufficient to permit their isolation from the milk. Thus, the rejection of record would apply to Claim 59, if entered.

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Continuation Sheet (PTOL-303)

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

As for the remainder of the response, Applicants' arguments, directed to the proposed claim amendments, are moot because the proposed amendment has not been entered for the reasons noted above.

In view of the proposed amendments, if entered, the rejections of Claims 39 and 40 would be withdrawn and Claims 39, 40, and newly proposed Claims 60-63 would be allowable.

The rejections are maintained for reasons of record.